Randomized Controlled Clinical Trial for Verifying the Effect of Silicone-Based Resilient Denture Liner on the Masticatory Function of Complete Denture Wearers

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> Purpose: The purpose of this study was to investigate whether application of permanent silicone-based resilient denture liner (SR) to mandibular complete dentures significantly improves patients' masticatory ability compared to conventional heat-activated acrylic resin (AR). Materials and Methods: Twenty-eight edentulous patients were randomly placed into 1 of 2 crossover groups (AR-SR/SR-AR) by using a random permuted block within strata method. The AR-SR group received AR denture treatments followed by SR denture treatments. The SR-AR group received treatments in the reverse sequence. The outcomes were classified by matiscatory performance, mandibular movement, electromyographic activity, and maximum occlusal force. Results: No significant differences were observed in any of the baseline characteristic measurements between groups. SR denture wearers exhibited significantly higher masticatory performance than AR denture wearers. SR denture wearers exhibited a longer early-stage occluding period than AR denture wearers. There were no differences in electromyographic activity between the AR and SR groups. There were no significant differences in maximum occlusal force between the AR and SR groups. *Conclusion:* This study showed that the application of SR to mandibular complete dentures resulted in significant improvements to the patients' masticatory ability compared to AR. Int J Prosthodont 2006;19:593-600.

Despite significant advancements in dentistry for saving teeth that previously were subject to extraction, there are literally millions of people throughout the world who have replaced their diseased teeth with dentures.¹

For decades, implant therapy has been one of the notable treatment options for edentulous patients. One study highlighted the possible significant benefits for edentulous patients when using the implant technique.^{2–4} The McGill consensus statement suggested

that a mandibular implant overdenture is a very powerful tool for edentulous patients.⁵ Many patients, unfortunately, are unable to benefit from implant treatment because of medical, psychological, or financial constraints. Therefore, conventional complete dentures remain a very important therapy for edentulous patients.

Some complete denture wearers experience pain while eating during their daily meals, because their alveolar ridge mucosa is too atrophic and thin to bear the stress caused by occlusal force. The use of resilient denture liners for edentulous patients with an atrophic alveolar ridge is a very effective method for reducing the painful effects related to occlusal force.⁶ In addition, the recent concept that resilient denture liners, when used intelligently, are an excellent adjunct in removable prosthodontics,⁷ was very attractive for the authors. These sentiments motivated the authors to conduct the present trial.

Resilient denture liners have been used for decades and are actively studied in dental materials^{8,9} and bacteriologic fields¹⁰; however, few significant reports on their clinical efficacy have been published. Based on a

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Fig 1 The study design.

randomized controlled trial that focused on the patients' subjective outcomes, it was previously reported that patients preferred complete dentures fabricated with resilient denture liner.¹¹ In the present study, the objective outcomes related to mastication were documented. The null hypotheses were: no differences of masticatory performance, mandibular movement, electromyographic (EMG) activity, or maximum occlusal force between the conventional heatactivated acrylic resin (AR) denture wearer and the permanent silicone-based resilient denture liner (SR) denture wearer. The purpose of this study was to investigate whether the application of SR to mandibular complete dentures resulted in significant improvements in the patients' mastication compared to AR.

Materials and Methods

Study Population

Edentulous patients at Nihon University School of Dentistry at Matsudo Affiliated Hospital, Chiba, Japan, who were willing to undergo new complete denture treatments were selected to participate in the study. The exclusion criteria were: (1) systemic or neurologic disease; (2) lack of understanding of written or spoken Japanese; and (3) fewer than 2 years of elapsed time since the final tooth extraction(s). Written informed consent was secured from all patients. The study protocol was approved by the Human Ethics Committee at Nihon University School of Dentistry at Matsudo (Issue no. EC01–001).

Study Design

A randomized controlled clinical trial with a 2-period crossover was conducted from February 2000 to

August 2002. A random permuted block within-strata method¹² was used for allocating gender in equal proportions to both groups. Subjects were randomly allocated using a computer-generated random-number table into 1 of 2 crossover groups (AR-SR/SR-AR). Both groups received 2 sets of maxillary and mandibular complete dentures. The AR-SR group received the AR denture followed by the SR denture, and the SR-AR group received the dentures in the reverse sequence (Fig 1). The duplicated denture was fabricated by placing the artificial teeth (Endura, Shofu) and molten wax into the silicone mold, comprised of silicone impression material (Duplicone, Shofu), that completely covered the artificial teeth and the polished denture surface. Similar occlusion was accomplished by occlusal equilibration of the wax denture after mounting the duplicated working model on the articulator (Hanau H2, Teledyne Waterpik) at the same occlusal position by using the same occlusion record with occlusion rim. AR dentures were fabricated with conventional heat-activated AR (Urban, Shofu). SR dentures were fabricated with conventional heat-activated AR and a 2-mm-thick permanent silicone-based denture liner (Sofreliner MS, Tokuyama). One month after the completion of denture adjustments, the subjects returned to the clinic 3 times at 1-month intervals for assessment of their level of masticatory performance. Mandibular movement, EMG activity, and occlusal force were measured only 3 months after the completion of denture adjustments had passed. All treatments were performed by 1 prosthodontist. Blinding to the intervention was not feasible, since it was clear to both the patients and clinicians which materials were used. Sample size was based on the primary outcome of the research, general satisfaction, which was measured on a 100-mm visual analog scale. A total of 23 subjects were required to have 80% power with a 2-sided alpha level of 5%. In consideration of potential dropouts, 28 subjects were enrolled in the study. A detailed description of how the 2 types of dentures were fabricated and the study design has been previously published.¹¹

Baseline Measurements

The baseline characteristics of age, gender, edentulous period, age of existing denture, number of previous dentures, height of alveolar ridge,¹³ and general satisfaction as measured by a 100-mm visual analog scale¹¹ were collected by an assessor (Table 1).

Masticatory Performance

Masticatory performance was measured by the sieving method using 3-g peanuts for 20 cycles on the pre-ferred chewing side.¹⁴

Mandibular Movement and EMG Activity

Mandibular movement at the lower incisal point during chewing was recorded using the BioPack system (Bioresearch). The magnet was attached to the artificial mandibular central incisors of the complete denture using autopolymerizing acrylic resin. The long axis of the magnet was set parallel to the horizontal plane to allow sliding contact of the mandible in every direction. The sensor carrying the head frame of the Biopack system was centered for each subject according to the magnet's location and oriented to the Frankfort horizontal plane.

The EMG activity during chewing was recorded using a Polygraph 360 system (Nippon Denki San-ei). The myoelectric signals of the left and right masseters and the left and right anterior temporal muscles were recorded by bipolar surface silver/silver-chlorine disk electrodes placed approximately 1.5 cm apart in the direction of the muscle fibers under 2 KHz sampling frequency. The subjects sat comfortably with the Frankfort plane nearly parallel to the ground. The subjects were asked to chew a peanut (1 g) on their preferred side. Measurements were conducted 3 times for each test. During chewing, the mandibular movements and EMG activities were simultaneously sampled. The total chewing strokes and muscular activities were divided into 3 stages of initial, middle, and final, from which 5 consecutive stable strokes were selected for the calculation of the mean and SD. The parameters for the mandibular movements, such as opening time, closing time, occluding time, and the complete time (defined as cycle time), were calculated using the Biopack (Bioresearch) software program. The integrated values for all myoelectric activity were calculated using the AcqKnowledge III (Bioresearch) software program.

Table 1	Baseline Characteristics (SDs) of the 28 Subjects
Enrolled in	n the Trial*

	AR-SR (n = 14)	SR-AR (n = 14)
Age (y)	71.7 (7.0)	69.4 (6.6)
Gender (male/female)	7/7	6/8
Edentulous period (y)	11.3 (8.0)	13.5 (8.0)
Age of existing denture (y)	7.9 (6.7)	6.0 (7.6)
No. of previous dentures	3.0 (3.4)	2.6 (1.2)
Height of alveolar ridge (mm)	19.0 (5.7)	19.5 (5.5)
General satisfaction [†]	40.5 (28.5)	47.3 (33.4)

*No significant differences between the groups.

[†]Measured using a 100-mm visual analog scale.

Maximum Occlusal Force

This measurement system consisted of pressure-sensitive sheets (Dental Prescale, Fuji) and an analyzing computer (Occluzer FPD703, Fuji). The subjects were instructed to bite the pressure-detecting sheet with maximum occlusal force in the intercuspal position. The computer analyzed the area and density of each impressed mark from the digital image of the dental arch on the sheet. The measurements were repeated 3 times, and the mean and SD were then calculated.

Statistical Analysis

Comparison of the participants' baseline characteristics between the AR-SR and SR-AR denture groups were tested using the *t* test, except for the proportion of gender, which used the chi-square test. Differences in the masticatory performance between the existing dentures at baseline and for both of the new dentures 1 month after the completion of denture adjustments were investigated using the paired t test. Differences in masticatory performance between the AR and SR dentures were tested using 2-way analysis of variance (ANOVA) and the Bonferroni multiple-comparison post hoc test. The effects of wearing order on masticatory performance were tested using 2-way ANOVA. The differences between parameters, such as mandibular movement, EMG activity, and occlusal force, between the wearers of the AR and SR dentures were examined using the paired t test. All tests were 2-tailed, with $P \le$.05 indicating statistical significance. All analyses were performed as per the intention-to-treat (ITT) principle,^{15,16} ie, the data from dropout subjects who had data from at least 1 denture were included in the analysis. The last available data before dropout were used for the outcome's missing data. All statistical analyses were performed on a personal computer with SPSS II for Windows (SPSS).



Results

2 mo

3 mo

First period: SR denture

Second period: SR denture

Subjects

20

10

0

c

1 mo

Twenty-eight consecutively sampled patients (50 to 80 years of age) were randomized for the crossover trial. The random permuted block within-strata method assigned an equal number of patients to each group (n = 14). Table 1 shows the baseline characteristics of the 28 subjects. No significant differences were observed in any of the characteristics of the baseline measurements between the AR-SR and SR-AR groups (P > .05, t test and chi-square test). Of the 28 subjects, 20 completed the trial and 8 dropped out. Three subjects dropped out before the completion of the denture adjustments during the first period, and 5 dropped out because of a lack of interest in continuing with the trial after receiving 1 denture. Since 3 dropout subjects did not receive even 1 denture and failed to make an assessment, their data were excluded from the analysis. Five dropout subjects had at least 1 set of masticatory



Figs 2a to 2c Results for masticatory performance: (a) changes between the groups; (b) effect of wearing order on the AR dentures; (c) effect of wearing order on the SR dentures.

performance data from a newly delivered denture, and 2 dropout subjects had first period mandibular movement and EMG data. Therefore, their data were included in the ITT analysis (see Fig 1).

Masticatory Performance

The masticatory performance of AR and SR denture wearers at 1, 2, and 3 months after the completion of denture adjustments showed significant improvement compared to the existing dentures (P < .01, paired t test) (Figs 2a to 2c). The SR denture wearers showed better masticatory performance than AR denture wearers 1 and 2 months after the completion of denture adjustments, although the differences were not significant at 1 month (P<.01, 2-way ANOVA and Bonferroni multiple-comparison post hoc test) (Fig 2a). The masticatory performance with AR dentures did not change over time (P>.05, 2-way ANOVA and Bonferroni multiple-comparison post hoc test); however, for the SR dentures, the masticatory performance improved sig-

	Initial phase		Middle phase		Final phase	
	AR	SR	AR	SR	AR	SR
Cycle	657.8 ± 141.6	673.5 ± 123.9	681.9 ± 139.9	684.9 ± 112.0	761.8 ± 164.4	730.7 ± 141.1
Opening phase	153.1 ± 49.6	147.8 ± 38.6	157.3 ± 48.4	151.5 ± 40.9	185.5 ± 52.0	171.1 ± 41.6
Closing phase	244.4 ± 55.4	233.0 ± 43.4	206.1 ± 42.2	205.3 ± 28.5	224.1 ± 36.3	203.3 ± 31.0
Occluding phase*	258.9 ± 50.7	292.8 ± 75.4	318.5 ± 68.8	328.1 ± 77.8	352.2 ± 92.9	355.6 ± 87.6

Table 2Mean (± SD) Values of Masticatory Movement (ms) for 22 Patients

*Significant differences between the groups at the initial phase.

Table 3 Mean (± SD) Values of EMG Activity (µvs) During Chewing for 22 Patients*

	Initial phase		Middle	Middle phase		Final phase	
-	AR	SR	AR	SR	AR	SR	
Working-side temporalis	20.1 ± 7.5	18.7 ± 6.1	18.8 ± 6.8	17.6 ± 5.8	18.1 ± 6.9	16.9 ± 5.5	
Working-side masseter	21.0 ± 8.0	25.6 ± 13.6	19.8 ± 8.7	24.2 ± 13.8	19.8 ± 10.5	23.0 ± 14.0	
Balancing-side masseter	12.8 ± 6.0	13.8 ± 7.2	11.9 ± 6.0	11.7 ± 6.4	10.9 ± 6.3	10.4 ± 5.1	
Balancing-side temporalis	14.9 ± 6.2	15.2 ± 5.1	14.8 ± 7.3	14.6 ± 5.5	13.7 ± 7.8	13.1 ± 5.3	

*No significant differences between the groups.

nificantly after 2 and 3 months compared to after 1 month (P < .01, 2-way ANOVA and Bonferroni multiple-comparison post hoc test). AR denture wearers during the second period exhibited the same masticatory performance as the SR denture wearers during the first period (P > .05, 2-way ANOVA) (Fig 2b); however, the SR denture wearers during the second period exhibited significantly better masticatory performance than they did during the first period (P < .05, 2-way ANOVA) (Fig 2c).

Mandibular Movement

Analysis of the mandibular movement during mastication showed that the early stage of the occluding phase for SR denture wearers was longer than that of AR denture wearers (P < .05, paired *t* test) (Table 2); however, the other segments of mandibular movement, such as opening time, closing time, and the middle and late phases, did not show any differences between the AR and SR groups (P > .05, paired *t* test).

EMG Activity

Analysis of EMG activity during mastication indicated no statistical differences between the AR and SR denture wearers in all muscles, such as working-side temporalis, working-side masseter, balancing-side masseter, and balancing-side temporalis, as well as all related phases (early, middle, and late) (P>.05, paired *t* test) (Table 3).

Maximum Occlusal Force

The maximum occlusal force was 249.3 \pm 114.7 N for AR denture wearers and 262.5 \pm 125.2 N for SR denture wearers. This difference was not statistically significant (*P* > .05, paired *t* test).

Discussion

This crossover clinical trial indicated that a complete denture with resilient denture liner provided better masticatory performance than a conventional complete denture. To investigate why the resilient denture liner provided better masticatory performance, the mandibular movement, myoelectric activity during mastication, and maximum occlusal force were measured. Analysis of every outcome showed that only the early stages of the occluding phase for the SR denture wearers were longer than those of the AR denture wearers. Humans can masticate foods the most effectively when the clearances between the maxillary and mandibular molars are within 2 mm.¹⁷ In addition, clenching intensity increases in the intercuspal position.¹⁸ These findings support the belief that the chewing cycle near the occluding phase is important for mastication, as the longer occluding time obtained by the resilient denture liner provided patients with better masticatory performance.

Significantly longer occluding time for the SR denture wearers was observed during only the early stages. This suggests that the effects of the resilient denture liner appear during the most difficult stages of the entire masticatory process. The food texture and size would gradually change over time and greatly influence the mandibular movements.^{19,20} The early stages of mastication are considered difficult for complete denture wearers compared to the middle and late stages, since the food bolus may retain the initial texture and size, both of which place high pressure on the supporting structures during mastication.^{18,21} Shim and Watts²² reported that the resilient denture liner has a stress distribution effect. In addition, it was reported that the resilient denture liner permits a wider dispersion of forces and absorption of impact forces involved with the functional and parafanctional movements.⁷ The resilient denture liner upgraded masticatory function and enabled the SR denture wearers to overcome chewing difficulties during the early periods. In contrast, the resilient denture liner did not influence the middle and late stages of the occluding time, since the texture and size of the bolus made it gradually easier to chew. Since the bolus in the middle and late stages was sufficiently soft and small, both AR and SR denture wearers were able to chew effectively.

The fact that the occluding phase was longer for SR denture wearers than for AR denture wearers may be explained by 2 factors: (1) the sensory input from the mucosa supporting the denture, and (2) the mechanical property of the resilient denture liner. The sensory input from denture-supporting mucosa, which is applied on the premolar region by a metal half hemisphere, allowed for a short occluding phase for complete denture wearers.²³ This study showed that the occluding phase for complete denture wearers was closely related to the stimulation of pressure on the mucosa supporting the denture, derived from the occlusal force. Furthermore, it was documented that the flex, controlled by sensory inputs from the mucosa, may stop the closure of the arch from protecting the mucosa from excessive pressure.24 This implies that the magnitude and nature of the pressure on the mucosa resulting from occlusal force could change the occluding phase during the chewing cycle. The resilient denture liner may control the pressure on the denturesupporting mucosa, since the mechanical properties of the resilient denture liner provide relief and reduce the stress caused by chewing.²² This property would prolong the threshold time that is dependent on the stress, since the storage of stress in the mucosa would be delayed because of the stress relief. Consequently, it was concluded that SR denture wearers would exhibit a longer occluding phase and exhibit better masticatory performance than AR denture wearers.

The better masticatory performance of SR denture wearers could not be explained by EMG activity during mastication or maximal occlusal force. In consideration of the authors' previous report,¹¹ it was reasonable to believe that there would be no difference in EMG activity during mastication between the AR and SR dentures, since both types of denture wearers expressed very high levels of satisfaction regarding the dentures' function. It was also assumed that in this case the EMG measurements would not have the sensitivity necessary to distinguish the slight amount of difference between AR and SR denture wearers. In contrast to the present results, one study reported that EMG activity and maximum occlusal force were improved by applying a resilient denture liner on a complete denture.²⁵ In the study, the subjects wore only 1 denture throughout the whole trial, in which the denture base was relined using the resilient denture liner during the second period of the trial. The outcomes were measured twice, first before reline and again after reline. The study design, a 1-way crossover trial, emphasized the effect of the dentures in the second period moreso than in the first, since the wearing time was accumulated. Consequently, the difference became significantly larger than the true difference, thus implying a bias. The present trial, however, overcame this bias by using a 2-way randomized crossover trial. The disparity of the results was assumed to result from the study design.

The question to be considered, since both outcomes were measured using the same high-quality dentures, is why did the resilient denture liner affect masticatory performance more than maximum occlusal force? It was assumed that maximum occlusal force was dependent only on static compression, whereas the masticatory performance was dependent on both static and dynamic compression during the chewing cycle. While the denture is functioning, the denture-supporting mucosa receives significantly more stress during biting. The stress was controlled by the resilient denture liner, since it permits a wider dispersion of forces and absorption of impact forces that are involved in functional and parafanctional movements.⁷ This is perhaps why the resilient denture liner affected masticatory performance significantly more than maximum occlusal force.

The masticatory performance of the AR group remained at the same level during the 3 months of recall, while the masticatory performance of the SR group improved from 1 to 2 months and remained the same through 3 months. One study reported that no changes in the masticatory performance from 1 day to 6 months after denture delivery were observed in complete denture wearers with a conventional denture base.¹⁷ The current study is in agreement with those findings. The difference in the masticatory performance changes between the SR and AR denture wearers implied that the adapting process of mastication might vary based on the type of denture base material.

It was possible to verify the differences in the adaptation process in the masticatory performance by between-subject analysis comparing the first wearing order of SR and AR dentures with the second wearing order of the dentures. The masticatory performance of the SR denture wearers during the second period was better than that of the first period; however, the masticatory performance of the AR denture wearers during the second period was not affected by the wearing order. This implies that the SR denture wearers experienced a different adapting process from the AR denture wearers and would gradually obtain the necessary skills for mastication by repeating a daily practice of food mastication. As a result, when clinicians provide a complete denture with a resilient denture liner, they should inform the patients that the masticatory function will (1) gradually improve by daily wearing, (2) feel different from conventional dentures, and (3) continue to improve for several months after the completion of denture adjustments. This explanation is very important in real-world, daily practice, since patients experiencing pain from their complete dentures for a long period of time would likely give up using their denture before obtaining the necessary skills.

This randomized controlled clinical trial with a prosthodontically wide spectrum of consecutively sampled subjects can be statistically generalized to the edentulous patient population with a high degree of probability. However, it should be acknowledged that there are limitations to this study, and the results may not be applicable to all edentulous patients. Therefore, an in-depth investigation of the exceptions and indications for a permanent resilient denture liner is needed. Additionally, residual ridge reduction has been one of the central points of discussion in the field of resilient denture liners since Woelfel et al²⁶ reported bone loss caused by an improperly used denture liner in 1965. One study reported that the rate of ridge reduction of dentures with a resilient layer was significantly less than that of conventional dentures.²⁷ Unfortunately, the follow-up period for this study was only 6 months. The outcome related to residual ridge reduction is still an important area of interest for clinicians. This study has lost the opportunity for a followup study of the residual ridge reduction, since many patients selected the SR denture and only a few subjects remain as a control.¹¹ The authors, however, are conducting a parallel randomized controlled clinical trial that does include the objective of determining the outcome related to residual ridge reduction over a longterm observation period.

Conclusions

The mandibular complete denture with a permanent silicone-based resilient denture liner provided edentulous patients with better masticatory performance compared to a conventional denture base material. Prolongation of the early stages of the occluding phase was observed in the SR group; however, differences regarding EMG activity or maximum occlusal force were not observed. This study showed that the application of permanent silicone-based resilient denture liner on mandibular complete dentures significantly improved patients' masticatory function compared to a conventional heat-activated acrylic resin.

Acknowledgments

The authors gratefully acknowledge the assistance and cooperation of Dr Manabu Kitamura. His invaluable input from the start until the end of this study was highly significant and greatly valued. This study was conducted with assistance from the Japan Society for the Promotion of Science (Grant-in-Aid for Scientific Research no. 15592071).

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Literature Abstract

Effect of postoperative radiotherapy on the functional results of implants placed during ablative surgery for oral cancer

The purpose of this retrospective study was to investigate the survival of dental implants placed in ablative surgery patients diagnosed with oral squamous cell carcinoma (SCC) with or without adjuvant postoperative radiotherapy. Forty-eight consecutive edentulous patients (29 males and 19 females) with primary oral SCC treated from 1996 to 2003 were included in this study. Two to 4 Brånemark Mk II/III 2 implants were inserted in the interforaminal region of the mandible. If postoperative radiotherapy occurred, the implants were always in the radiation field. Chi-square test was used to compare the 2 groups with regards to the time interval between implant insertion and abutment placement and the number of soft tissue corrections. Twenty-one patients (61 implants) received postoperative radiotherapy and 27 patients (78 implants) did not. There was a statistically significant difference (P = .01) between the average time in months between insertion of implants and abutment placement for both groups (radiotherapy group = 9 [SD: 3.6], nonradiotherapy group = 4.7 [SD :1.9]). No difference was found between the 2 groups regarding the mean number of denture adjustments until satisfaction and soft tissue corrections around the implants (P = .06). Success rates of osseointegration were 97% in the irradiated group compared to 100% in the nonirradiated group. The prosthetic success rates were lower because in 12 patients (34 implants), a functional denture was not fabricated due to recurrence (7 patients, 22 implants) or for psychologic reasons (4 patients, 12 implants). The results of this pilot retrospective study suggest that postoperative radiotherapy does not affect the osseointegration of dental implants placed during tumor ablation surgery or the ultimate function of the overdentures.

Schepers RH, Slagter AP, Kaanders JHAM, van den Hoogen FJA, Merkx MA. Int J Oral Maxillofac Surg 2006;35:803–808. References: 23. Reprints: Dr MA Merkx, Department of Oral and Maxillofacial Surgery, 421 Radboud University, Nijmegen Medical Center, PO Box 9101, NL-6500 HB Nijmegen, The Netherlands. E-mail: m.merkx@mkc.umcn.nl–Alvin G. Wee, OSU College of Dentistry, Columbus, OH

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